

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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| Applicant | : | Rodney William Kelly |) | Examiner: |
| | | |) | Prema M. Mertz |
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| For | : | COMPOSITIONS FOR THE TREATMENT |) | |
| | | OF AUTOIMMUNE DISORDERS |) | |
| | | |) | |

RESPONSE TO RESTRICTION/ELECTION OF SPECIES REQUIREMENT

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This submission is in response to the office action dated March 17, 2008.

In response to the written restriction requirement, applicant hereby elects Group I (Claims 1-2, 5-6, 7-10, 12-14, 16 and 20-26) with traverse.

The U.S. Patent and Trademark Office ("PTO") asserts that Groups I-VII do not relate to a single general inventive concept, because Piquet-Pellorce et al., "Prostaglandin E2 Potentates Granulocyte-Macrophage Colony Stimulating Factor-Induced Histamine Synthesis in Bone Marrow Cells: Role of cAMP," *Life Sci.*, 48:2377-2382 (1991) ("Piquet-Pellorce") teaches a method of administering prostaglandin E2 ("GE2") and granulocyte-macrophage colony stimulating factor ("GMCSF"). Applicant respectfully disagrees.

Applicant submits that Groups I-VII describe a common general inventive concept required under PCT Rule 13.1, and should be examined together. Groups I-VII each include common claims 1-2, 7-10, 12-14, 16, 20-22, and 23-26, and are directed to a method of inducing tolerance to an antigen in a patient by administering an agent which raises the effective cAMP concentration in a monocyte cell and GMCSF or derivative thereof.

Piquet-Pellorce teaches (in the context of assessing the role of histamine in haematopoiesis) that the combination of PGE2 and GMCSF increases intracellular cAMP and induces histamine synthesis in bone marrow cells, but does not teach or suggest that the combination of PGE2 and GMCSF can be used for inducing tolerance to an antigen, as set forth in claim 1.

For these reasons, unity exists for Groups I-VII, and all claims of Groups I-VII (i.e., claims 1-10, 12-14, 16, and 20-26) should be examiner together.

In response to the election of species requirement, applicant hereby elects, with traverse, the following species:

- (i) Prostaglandin E2 as the prostaglandin which raises the effective cAMP concentration in a monocyte cell; and
- (ii) "locally at a site where tolerance is required" as the method of administering an agent.

Claims that read on the elected species include claims 1-2, 5-6, 7-10, 12-14, 16 and 20-26.

Applicant respectfully traverse the election of species requirement on the basis that the position asserted by the PTO—that prostaglandins, cAMP analogues, and PDE inhibitors are structurally and functionally distinct chemical compounds and do not relate to a single general inventive concept because these species lack the same or corresponding special technical features—is improper. Prostaglandins, cAMP analogues, and PDE inhibitors do share a unifying technical feature, as required by PCT Rule 13.2, by their ability to raise the effective cAMP concentration in a monocyte cell, which is directly relevant to the claimed method of inducing tolerance to an antigen. The species, therefore, share similar function. For this reason, the election of species requirement should be withdrawn.

Respectfully submitted,

Date: April 15, 2008

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